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EXAMINER	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MARINUS GERARDUS CORNELIS KIVITS,
ANDOR WILHELM JOSEPH HENDRICKS,
and LEONARD FRANCISCUS MALLEE

Appeal 2010-000020
Application 10/089,995
Technology Center 1600

Before ERIC GRIMES, TONI R. SCHEINER, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

This is an appeal under 35 U.S.C. § 134 involving claims to a process of purifying growth factors. The Examiner rejected the claims as not being

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

enabled for their full scope. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

Statement of the Case

Claims 16-23 and 33-35 are pending and on appeal (App. Br. 1). We will focus on independent claim 16 which reads as follows:

> 16. A process for extracting transforming growth factor β (TGF-β) and insulin-like growth factor 1 (IGF-1) from a milk product, comprising the steps of
>
> a) recovering a basic fraction from the milk product by cationic exchange chromatography;
>
> b) passing the fraction obtained in step a) over a hydroxyapatite column;
>
> c) eluting the hydroxyapatite column sequentially with at least two eluents of increasing salt concentration or pH, said eluents being selected from phosphate buffers, sodium chloride solutions and potassium chloride solutions, wherein the first eluent has a pH of 5.5 to 7 and a salt concentration of 0.05 to 0.2 M and the second eluent has a pH of 5.5 to 7 and a salt concentration of 0.2 to 0.3 M, to obtain two separate fractions:
>
> i) a fraction comprising IGF-1, wherein the ratio IGF-1 to TGF-β is greater than 10:1;
>
> ii) a fraction comprising TGF-β, wherein the ratio TGF-β to IGF-1 is greater than 5:1.

The issue

The Examiner rejected claims 16-23 and 33-35 under 35 U.S.C. § 112, first paragraph because the Specification, while enabling in part, does not reasonably provide enablement for the full scope of the claims (Ans. 3-7).

The Examiner finds that:

> Without recitation of specific conditions, or a narrow range of conditions, the recited method, which requires the outcome of fractions of specifically identified characteristics comprising:
>
> i. a fraction comprising IGF-1 wherein the ratio of IGF-1 to TGF-β is greater than 10:1
>
> ii. a fraction comprising TGF-β, wherein the ratio of TGF-β to IGF-1 is greater than 5:1,
>
> is merely an invitation to experiment to determine which combinations of conditions would achieve the desired results.

(Ans. 4).

Appellants argue that "both independent claims 16 and 33 recite recovering a basic fraction from a milk product via cationic exchange chromatography" (App. Br. 5). Appellants argue that "with this information alone, one skilled in the art would select a suitable buffer, salt concentration, and pH level suitable for recovering a basic fraction from a milk product by cationic exchange chromatography" (App. Br. 5).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that undue experimentation would have been required to enable the full scope of claim 16?

Findings of Fact (FF)

Breadth of Claims

1. Claim 16 is drawn to a process for extracting TGF-β and IGF-1 from a milk product by column chromatography (*see* Claim 16).

2. Claim 16 does require recovering a basic fraction of a milk product by cationic exchange column followed by binding and eluting TGF-

β and IGF-1 on a hydroxyapatite column using particular buffers or salt solutions and particular pH or salt concentrations (*see* Claim 16).

Presence of Working Examples

3. Example 1 of the Specification teaches isolation of TGF-β and IGF-1 from milk, teaching specific columns, binding conditions, and elution conditions, which result in fractions where "[f]raction c) contains 100 µg IGF-1 . . . and is low in TGF-β . . . Fraction d) contains 660 µg TGF-β . . . and is low in IGF-1" (Spec. 9-10).

4. Example 2 of the Specification teaches isolation of TGF-β and IGF-1 from cheese whey (*see* Spec. 10-11)

5. Example 3 of the Specification teaches that the "purity of the IEC [ion exchange chromatography] fractions can be further increased by eluting the column under more stringent conditions. . . . Although the yield of growth factors and lactoperoxidase in this step is slightly lower, the specific activity of the growth factors present in this fraction is higher" (Spec. 11, ll. 5-16).

6. Example 4 of the Specification teaches that the "fractions bound on the hydroxyapatite column can also be separated using other elution conditions" (Spec. 11, ll. 20-21).

Amount of Direction or Guidance Presented

7. The Specification teaches that "[a]fter the absorption step the hydroxyapatite column is eluted sequentially with suitable eluting liquids. Possible eluents are phosphate buffers, sodium chloride and potassium chloride solutions. For the different fractions these eluents must have an increasing salt concentration" (Spec. 6, ll. 12-15).

8. The Specification teaches that it "is also possible to apply an increasing pH gradient. Other possible eluents are known to the person skilled in the art. It is preferred that the overall concentration range of the salt solutions used is between 0.01 to 1.0 M" (Spec. 6, ll. 15-17).

State of the Prior Art and Unpredictability of the Art

9. The Examiner cites Shing[2] as teaching isolation of growth factors by "elution with a 0.6M NaCl, pH 7.0" solution (Ans. 9).

10. The Examiner finds that Kussendrager[3] "is cited to indicate the wide range of specific salt concentrations and pH levels used to elute growth factors from a cationic exchange column" (Ans. 9).

11. Belford[4] teaches that "[c]ation-exchange chromatography effectively concentrates the cell growth activity present in whey and we have used this process . . . to characterise further the growth factors present in bovine milk" (Belford, abstract).

Quantity of Experimentation

12. The Examiner makes no findings regarding the quantity of experimentation required.

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[2] Shing et al., *Purification of Polypeptide Growth Factors from Milk*, 146 METHODS IN ENZYMOLOGY 42-48 (1997).
[3] Kussendrager et al., EP 0869134 A1, published Oct. 7, 1998.
[4] Belford et al., *Πλατελετ–δεριϖεδ γροωτη φαχτορ, ινσυλιν–λικε γροωτη φα χτορσ, φιβροβλαστ γροωτη φαχτορσ ανδ τρανσφορμινγ γροω τη φαχτορ β do not account for the cell growth activity present in bovine milk*, 154 J. ENDOCRINOLOGY 45-55 (1997).

Skill in the Art

13. The Examiner makes no findings regarding the skill level in the art.

Principles of Law

> When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application.

In re Wright, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993). "[T]he question of undue experimentation is a matter of degree. The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation 'must not be unduly extensive.'" *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996).

> Factors to be considered in determining whether a disclosure would require undue experimentation … include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

Analysis

The Examiner concludes that "the disclosure does not provide sufficient guidance to enable the skilled artisan, without undue

experimentation, to select a buffer of appropriate ionic strength and pH, among the myriad of possibilities set forth in the specification" (Ans. 8).

We are not persuaded. The claims are limited to particular columns, particular eluents, particular pH ranges and particular salt concentrations (FF 1-2). The Specification has multiple working examples using several different conditions for isolation of IGF-1 and TGF-β from milk or milk products (FF 3-7). The Specification teaches that "possible eluents are known to the person skilled in the art. It is preferred that the overall concentration range of the salt solutions used is between 0.01 to 1.0 M" (Spec. 6, ll. 15-17; FF 8).

None of the references cited by the Examiner suggest that there is any unpredictability whatsoever in purifying IGF-1 and TGF-β from milk or milk products, but the references simply use different purification procedures (FF 9-11). The Examiner provides no evidence that a large or undue quantity of experimentation would have been required to purify IGF-1 and TGF-β as required by the claims using different elution profiles, buffers, or conditions or that such experimentation would have been anything other than the routine and minimal experimentation necessary to optimize elution profiles during column chromatography.

Conclusion of Law

The evidence of record does not support the Examiner's conclusion that undue experimentation would have been required to use the full scope of claim 16.

SUMMARY

In summary, we reverse the rejection of claims 16-23 and 33-35 under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement.

REVERSED

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